DMID CLINICAL QUALITY MANAGEMENT PLAN FACT SHEET

Objective

By January 30, 2009, sites conducting DMID-supported clinical research must have a written Clinical Quality Management Plan (CQMP) which complies with the current DMID Clinical Quality Management Plan Policy, available on the NIAID public website, http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/quality.htm

Instructions for submission, review and acceptance, are provided, below.

Note: If your current CQMP pre-dates the current policy, confirm with the DMID Clinical Project Manager (CPM) or Program/Project Officer that the CQMP is both consistent with the research study being conducted and meets the DMID policy requirements.

Definitions

Quality Management (QM):	The overall system that includes all activities involved in quality assurance and quality control, including the assignment of roles and responsibilities, the reporting of results, and the resolution of issues identified during the review.
Quality Assurance (QA):	The periodic, systematic, objective, and comprehensive examination of the total work effort to determine the level of compliance with Good Clinical Practice (GCP) standards.
Quality Control (QC):	The real time ("day-to-day") observation and documentation of the sites work processes to ensure that accepted procedures are followed.
Clinical Quality Management Plan:	A written document that encompasses both Quality Assurance and Quality Control procedures and details the responsibility, scope, and frequency of these activities.

Clinical Quality Management Plan – Development

The DMID Clinical Quality Management Plan Policy, Sample Tools, and guidance listed below are available on the NIAID public website, http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/quality.htm

- DMID Clinical Quality Management Plan Policy
- DMID Clinical Quality Management Plan Fact Sheet
- Sample Chart Review Tool
- Sample Regulatory File Review Tool
- Sample Quality Management Summary Report
- Annotated Sample Clinical Quality Management Plan

The following are the basic components of a CQMP that are required by the DMID CQMP Policy:

- Plan Type: Site or Protocol Identification
- Responsibility
- Quality Management Process Descriptions (QA/QC and Record Selection)
- Key Quality Indicators
- Regulatory File Review
- Tools, Checklists, and Reminders
- Staff Training/Qualifications
- Quality Management Summary Reports
- Site Evaluation of the CQMP

Clinical Quality Management Plan - Submission, Review, and Acceptance

- **Submission:** For many sites, written agreements with DMID require sites / principal investigators to proactively submit clinical quality management plans for review and acceptance by DMID. For other sites, DMID may request a copy of a site or protocol-specific CQMP for review and acceptance, as DMID deems appropriate. Submit the site or protocol-specific CQMP electronically to DMID_QMP_Reviewers@lists.ppdi.com.
- **Review:** CQMPs requested by DMID are reviewed against the DMID basic requirements outlined in this policy. This responsibility may be delegated to the DMID Clinical Trials Management (CTM) contractor.
- **Acceptance**: Following resolution of the CQMP review, DMID will provide a written notification of acceptance to the PI/designee.

Questions?

Regarding the submission requirement for the CQMP, contact the DMID Clinical Project Manager, Project/Program Officer assigned to the investigative site or specific protocol.

For questions about the policy, tools and guidance, contact Claudia Baxter, RN, baxterc@niaid.nih.gov

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